UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

PURDUE PHARMA L.P. et al, Plaintiffs, v. COLLEGIUM PHARMACEUTICAL, INC., Defendant.	C.A. No. 15-cv-13099-FDS (Lead Docket No.)

MEMORANDUM OF LAW IN OPPOSITION TO COLLEGIUM'S MOTION FOR PARTIAL JUDGMENT AND COLLEGIUM'S MOTION FOR EXPEDITED HEARING, AND IN SUPPORT OF PURDUE'S CROSS-MOTION FOR A PARTIAL STAY

I. INTRODUCTION

Plaintiffs Purdue Pharma L.P. et al. ("Purdue") oppose Defendant Collegium Pharmaceutical, Inc.'s ("Collegium") Motion for Partial Judgment (ECF No. 26) on three of the five patents at issue between Purdue and Collegium, and its Motion for Expedited Hearing (ECF No. 23). Purdue further cross moves, pursuant to the inherent power of this Court to control its docket, for a temporary stay of proceedings as to those three patents until the Federal Circuit rules on their validity in a pending appeal, currently *sub judice*, from the district court judgment on which Collegium relies for its assertion of invalidity.

Collegium's Motions should be denied because they ignore two important facts. *First*, although Collegium claims that judgment on three of the asserted patents is "the only thing standing in the way of Collegium receiving final approval from FDA" (ECF No. 24 at 2), Collegium ignores that it cannot launch its accused product before April 16, 2016, even if judgment were entered in favor of Collegium on those patents. Collegium currently has only tentative approval from FDA, and cannot obtain final FDA approval in order to launch its

accused product until at least April 16, 2016, because FDA has acknowledged that Purdue holds "data exclusivity" based on certain clinically proven abuse-deterrent properties. This exclusivity should prevent FDA from issuing final approval of Collegium's product during that period exclusivity. *Second*, the Federal Circuit will likely decide the pending appeal on those three patents by early February 2016—well before April 16, 2016. Given that imminent decision on three of the asserted patents, there is no reason to expedite this case or rush any part of it to judgment.

To the contrary, proceedings on these three patents should be stayed at least until the Federal Circuit decides the pending appeal. If the Federal Circuit reverses or vacates the judgment of invalidity that is on appeal, the collateral estoppel-based Rule 54(b) judgment that Collegium seeks would be for naught. Moreover, Purdue would have to appeal such a Rule 54(b) judgment in order to preserve its right, and both this Court and the Federal Circuit would have to undo that judgment as well. Given the imminent resolution of the already pending appeal, the most prudent and efficient course is to stay this case until that appeal concludes. Accordingly, Purdue respectfully submits that this Court should deny Collegium's Motions as premature, and issue a temporary stay of proceedings regarding the three challenged patents pending a decision in the Federal Circuit appeal. Meanwhile, proceedings on the other two asserted patents should continue.

II. BACKGROUND

A. Purdue's OxyContin® Product and Litigation History

Purdue developed OxyContin®, the first and only FDA-approved abuse-deterrent, extended-release oxycodone product, which has been a medically and commercially successful treatment for moderate to severe pain, such as chronic cancer pain. During its development,

Purdue scientists made numerous patented inventions, including the patents asserted against Collegium: (i) U.S. Patents Nos. 7,674,799, 7,674,800, and 7,683,072 ("the Listed Patents"),[1] which are directed to oxycodone API with very low levels of a potentially genotoxic impurity; (ii) U.S. Patent No. 8,652,497 ("the '497 patent"), which discloses and claims deterring drug abuse through the use of irritants in the formulation; and (iii) recently issued U.S. Patent No. 9,073,933 ("the '933 patent"), from the same family as the Listed Patents (and also listed in the Orange Book), but with different claims.[2]

Purdue previously brought suit against Teva Pharmaceuticals USA and various other defendants in *Purdue Pharma L.P. v. Teva Pharmaceuticals, USA, Inc.* (S.D.N.Y) (Stein, J.) for infringement of the Listed Patents with their generic copies of OxyContin®. The New York court determined that the Listed Patents were infringed and satisfied the disclosure and claiming requirements of 35 U.S.C. § 112, but were invalid for obviousness under 35 U.S.C. § 103. 994 F. Supp. 2d 367, 409, 438 (S.D.N.Y. 2014). Purdue appealed the invalidity ruling to the Federal Circuit, which heard oral argument on November 3, 2015. *See Purdue Pharma L.P. v. Epic Pharma, LLC*, No. 2014-1294 (Fed. Cir.) (the "*Teva* appeal"). The *Teva* appeal concerns issues of obviousness of the Listed Patents. If Purdue succeeds in reversing or vacating the judgment on appeal, the Listed Patents will continue in litigation here. If not, any issues of infringement of the Listed Patents in this action will likely be resolved. Based on published court data, the Federal Circuit is likely to decide the *Teva* appeal by early February 2016. *See*

[1] These patents are "listed" in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, known as the "Orange Book." Other drug applicants that rely on Purdue's research data for OxyContin® (like Collegium) must certify that they will not infringe any valid Orange Book patents. *See* 21 U.S.C. § 355(b)(2)(A).

[2] The Listed Patents and the '497 patent are at issue here. The '933 patent is at issue in related Case No. 15-13783-FDS, filed in this Court on November 6, 2015. (ECF No. 1, No. 15-13783 (D. Mass.).) That case has not been consolidated with this case.

http://www.cafc.uscourts.gov/sites/default/files/announcements/2010/stateofthecourt10.pdf (statistics from 2005 through 2010 showing that 75 to 83 percent of appeals before the Federal Circuit are decided within 90 days of oral argument).

B. Collegium's Xtampza™ ER Product and Limitations On Any Ability To Launch

In 2014, Collegium filed a New Drug Application ("NDA") under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FFDCA") (21 U.S.C. § 355(b)(2)), seeking to market abuse-deterrent extended-release oxycodone capsules.[3] Collegium's § 505(b)(2) application seeks FDA approval based, in part, on Purdue's clinical research on OxyContin®. *See* 21 U.S.C. § 355(b)(2).

On February 12, 2015, Collegium provoked this litigation by sending a Paragraph IV Notice letter to Purdue indicating that it seeks FDA approval before Purdue's Listed Patents expire. Purdue timely initiated this litigation in March 2015. As a result, the Hatch-Waxman Act automatically stays FDA approval of Collegium's product for 30 months (*i.e.*, until August 2017), pending resolution of litigation on the three Listed Patents. *See* 21 U.S.C. § 355(c)(3)(C). In its complaint, Purdue made plain that, given the pending *Teva* appeal from the New York case, and to avoid wasting litigation resources, Purdue would move to stay proceedings on the Listed Patents until the Federal Circuit's decision. *See* Compl. (ECF No. 1) ¶ 33.

FDA has not issued final approval of Collegium's product. Instead, on November 6, 2015, FDA sent a letter to Collegium reflecting only "tentative" approval of Collegium's NDA. Ex. A at 2 (stating that Collegium's NDA "is not deemed approved" at this time) (emphasis in

[3] Although Collegium filed an NDA under § 505(b)(2), instead of an Abbreviated New Drug Application ("ANDA") under § 505(j), the relevant Hatch-Waxman procedures for patent certification and initiating litigation are the same. *See* 21 U.S.C. §§ 355(b)(2)(A), 355(j)(2)(A)(vii).

original). In so doing, FDA recognized that final approval is subject to the 30-month stay arising from Purdue's patent exclusivity, but could also be subject to "data exclusivity" for OxyContin® until April 16, 2016—a form of non-patent marketing exclusivity under FFDCA § 505(c)(3)(E)(iv) based on the "conditions of approval" granted by FDA to Purdue on April 16, 2013, based on Purdue's abuse-deterrent clinical studies. At a minimum, Purdue's data exclusivity covers "addition of information regarding the intranasal abuse potential of OxyContin." Ex. B at 5-6 (capitalization altered).

Because the 30-month stay extends well into August 2017, FDA's tentative approval did not need to separately address Purdue's data exclusivity until April 16, 2016: "We need not determine at this time whether approval of your 505(b)(2) NDA for XTAMPZA ER would otherwise be blocked by another drug's marketing exclusivity expiring before termination of the 30-month stay." Ex. A at 2 n.1. This FDA statement recognizes that, even if the 30-month stay were not in place (or terminated), the April 2016 data exclusivity would still be in play. Purdue's data exclusivity should prevent FDA from granting final approval to Collegium's product before Purdue's exclusivity terminates on April 16, 2016, regardless of the status of any of Purdue's patents.

Outside of its Motions before this Court, Collegium has publicly and repeatedly stated that April 2016 is its earliest possible launch date for Xtampza™ ER—commensurate with Purdue's data exclusivity. For instance, on August 12, 2015, Collegium issued a press release stating that it was "actively building the infrastructure required to support a *potential April 2016 launch* of Xtampza." Ex. D at 1 (emphasis added); *see also* Ex. C. And on November 12, 2015—after receiving tentative FDA approval and filing its Motions—Collegium reiterated "a *potential April 2016 launch* of Xtampza ER, pending final approval by the FDA," in both a

public conference call and webcast for investors and another press release. Exs. E, F at 1 (emphasis added).

III. ARGUMENT

A Rule 54(b) judgment is proper only if, based on "an assessment of the litigation as a whole, and a weighing of all factors relevant to the desirability of relaxing the usual prohibition against piecemeal appellate review in the particular circumstances," there is "no just reason for delay." *Spiegel v. Trustees of Tufts College*, 843 F.2d 38, 43 (1st Cir. 1988). There is no reason why this Court should rush to enter a partial Rule 54(b) judgment now, when a decision in the *Teva* appeal is imminent, Purdue's data exclusivity should prevent immediate launch, and Collegium has already, and repeatedly, represented to the public that it will not launch its proposed drug for least another five months in any event.

These same reasons counsel in favor of a brief stay of proceedings on the Listed Patents until the Federal Circuit decides the pending *Teva* appeal. "The power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936). Here, a stay pending resolution of the *Teva* appeal to await guidance from the Federal Circuit will avoid wasteful litigation and motion practice.

A. Staying Judgment Until The Federal Circuit Rules Will Simplify Issues

The *Teva* appeal will necessarily resolve many issues in this litigation. The appeal involves three of the five patents that Purdue asserts against Collegium, and addresses whether the asserted claims would have been obvious. The Federal Circuit's decision on that issue will inform whether those three patents should proceed in this case. If the *Teva* judgment is ultimately affirmed, that will, as Collegium notes, eliminate the need for further litigation

regarding the Listed Patents. A reversal or vacatur in *Teva* may also simplify the scope of this litigation by providing guidance on the invalidity challenges raised in the prior litigation.

Courts routinely grant stays pending appeals of related proceedings that involve potentially dispositive issues. "Indeed, a typical reason is the pendency of a related proceeding in another tribunal." *Hewlett-Packard Co. v. Berg*, 61 F.3d 101, 105 (1st Cir. 1995) (citing *Landis*, 299 U.S. at 254). Such discretion is particularly warranted when an allegedly preclusive decision is under review: "Where the purportedly preclusive decision is subject to an appeal, the prudent course is to stay any determination on the second action while the appeal is resolved." *Hynix Semiconductor, Inc. v. Rambus, Inc.*, No. C-00-20905, 2009 U.S. Dist. LEXIS 10939, at *19 (N.D. Cal. 2009). "Although courts award stays in a wide variety of circumstances, they often do so when 'a higher court is close to settling an important issue of law bearing on the action.'" *Wing Shing Prods. (BVI) Ltd. v. Simatelex Manufactory Co.*, No. 01Civ.1044, 2005 WL 912184, at *2 (S.D.N.Y. Apr. 19, 2005). As then-Judge Ginsburg explained, "[a]ccording preclusive effect to a judgment from which an appeal has been taken . . . risks denying relief on the basis of a judgment that is subsequently overturned. Consequently, care should be taken in dealing with judgments that are final, but still subject to direct review." *Martin v. Malhoyt*, 830 F.2d 237, 264 (D.C. Cir. 1987). Applying these general principles, this Court has previously stayed litigation pending resolution of other potentially dispositive proceedings. *See, e.g.*, *EMC Corp. v. Parallel Iron, LLC*, 914 F. Supp. 2d 125 (D. Mass. 2012) (granting stay pending resolution of first-to-file issue in Delaware); *Boston Heart Diagnostics Corp. v. Health Diagnostics Lab., Inc.*, No. 13-13111, 2014 U.S. Dist. LEXIS 67711 (D. Mass. May 16, 2014) (granting stay pending patent reexamination); *In re Body Sci. LLC Patent Litig.*, No. 1:12-md-2375, 2012 U.S. Dist. LEXIS 158835 (D. Mass. Nov. 2, 2012) (same).

Courts have granted stays specifically in Hatch-Waxman litigation pending an appeal from a prior case because the Federal Circuit's guidance on asserted patents would greatly simplify issues going forward. For example, in *Cephalon*, *Inc. v. Sandoz Inc.*, the District of Delaware granted a stay in a Hatch-Waxman patent case on the eve of trial. No. 10-123, 2011 U.S. Dist. LEXIS 48259, at *4, *8 (D. Del. May 5, 2011). The same court had previously ruled the asserted patents invalid in a prior case, which ruling was on appeal to the Federal Circuit. *See id.* at *6. The court noted the efficiencies gained by such a stay, stating that "[i]f the Federal Circuit affirms the court's invalidity holding, there is no reason for trial and the expenses related thereto." *Id.* Similarly, in *SmithKline Beecham Corp. v. Apotex Corp.*, also a Hatch-Waxman case, the Eastern District of Pennsylvania granted a stay pending conclusion of appellate proceedings on two patents previously held invalid. No. 99-CV-4304, 2004 U.S. Dist. LEXIS 13907, at *12, *25 (E.D. Pa. July 16, 2004). The court observed that even a reversal of the invalidity rulings would simplify the case: "We also think that this litigation will likely be simplified even if the invalidity rulings concerning the '723 and/or '944 Patents are reversed on appeal." *Id.* at *27.[4]

[4] Collegium's cited collateral estoppel cases (ECF No. 27 at 7) are distinguishable on their facts. In *Pharmacia & Upjohn Co. v. Mylan Pharmaceuticals, Inc.*, when the district court ruled on collateral estoppel, the underlying prior judgment had not been appealed. 170 F.3d 1373, 1380 (Fed. Cir. 1999). In fact, the Federal Circuit noted that other factual circumstances may counsel against immediate judgment: "it may be preferable in a particular case for a district court to allow some time to pass . . . before according a judgment collateral estoppel effect." *Id.* at 1381. Here, with decision in the *Teva* appeal imminent, a stay is the preferred course. In *Novo Nordisk, Inc. v. Paddock Laboratories, Inc.,* the district court denied a stay, finding that the defendant there would be prejudiced "if its market entry is delayed," which is not the situation here. 797 F. Supp. 2d 926, 934 n.7 (D. Minn. 2011). Moreover, the Federal Circuit eventually *reversed* the inequitable conduct ruling that formed the basis for collateral estoppel in *Novo*; the *Novo* ruling stood only because a separate invalidity ruling was affirmed. *See Novo Nordisk, Inc. v. Paddock Labs., Inc.*, 515 F. App'x 889, 890 (Fed. Cir. 2013). If the preclusive ruling had been reversed in full, wasteful re-litigation would have likely ensued.

Collegium itself recognizes that waiting for a decision in the *Teva* appeal could resolve many issues in this case. At its November 12, 2015 public conference call and webcast for investors, Collegium's CEO and President stated, "We are hoping for a decision ***on this appeal*** as soon as possible because if the Purdue appeal is denied, the patents will be deemed invalid, and the lawsuit against Collegium becomes moot." *See* Q3 2015 Collegium Earnings Conference Call, Collegium Pharmaceutical Nov. 12, 2015, *available at* http://ir.collegiumpharma.com/phoenix.zhtml?c=253995&p=irol-EventDetails&EventId= 5210499 (at 7:29) (emphasis added). These statements confirm that the *Teva* appeal should be decided first.

B. The Stay Requested by Purdue Is More Efficient Than The Entry Of "Immediate Judgment" Sought by Collegium

Purdue's requested stay will almost certainly be short. Because the Federal Circuit heard oral argument in the *Teva* appeal earlier this month, a decision by February 2016 is likely. *See SmithKline,* 2004 U.S. Dist. LEXIS 13907, at *33 (granting a stay that "will remain in effect only until SmithKline exhausts its appeals"); *Wing Shing*, 2005 WL 912184, at *2 (granting stay pending appeal because "this is not to be a stay of indefinite duration"). In the vast majority of appeals before it—as high as 83%—the Federal Circuit issues its decision within three months of oral argument. *See* http://www.cafc.uscourts.gov/sites/default/files/announcements/2010/ stateofthecourt10.pdf. Here, that would be by early February 2016—well before April 16, 2016, the earliest date on which Collegium could launch its product.

However, if the Court were to enter judgment based on collateral estoppel, as Collegium requests, that could unnecessarily multiply proceedings. If no Rule 54(b) judgment is entered, it is undisputed that, if the Federal Circuit reverses or vacates the judgment of invalidity *as to even one asserted claim* of the Listed Patents, Purdue would be entitled to maintain the 30-month stay

while the parties litigate whether Collegium infringes Purdue's patent rights as the Hatch-Waxman Act contemplates. But if the Court entered judgment now, Purdue would immediately lose the 30-month stay that the Hatch-Waxman Act provides. *See* 21 U.S.C. § 355(c)(3)(C)(i)(I). Although that should be reversible, the law is not entirely consistent on this point. When preclusion is based on an earlier judgment subsequently altered on appeal, generally the "undoing of the first judgment will allow the second judgment to be undone as well—if it depended on the preclusive effect accorded to the first 'merits' judgment." *In re Kane*, 254 F.3d 325, 329 (1st Cir. 2001). But at least one court has suggested that termination of the 30-month stay is irreversible. *See Sanofi-Aventis v. FDA*, 725 F. Supp. 2d 92, 99 (D.D.C. 2010) (concluding that the 30-month stay terminates "without regard to the appellate process"). As such, if Purdue prevails in the *Teva* appeal, the premature judgment that Collegium requests may invoke an additional dispute, and corresponding briefing, as to reinstatement of the 30-month stay.[5]

Collegium's proposed judgment would also unnecessarily multiply proceedings regarding the other two patents in this case. Collegium argues that, if the 30-month stay for the Listed Patents is lifted by a Rule 54(b) judgment, Purdue can protect its rights regarding the two other patents by moving for a preliminary injunction. *See* ECF No. 24 at 5 n.1. That is not an efficient substitute. Such proceedings would be time- and cost-intensive, likely requiring expedited fact

[5] Collegium argues that because Purdue agreed to collateral estoppel based on the Listed Patents as to certain Defendants in New York once that district court issued its decision, the same should apply here. *See* ECF No. 24 at 9; ECF No. 27 at 6-7. But that ignores that the facts and circumstances of those litigations as a whole were very different from that here. Purdue agreed to enter collateral estoppel judgments as to those New York Defendants because (1) it could then immediately appeal those judgments and consolidate them with the pending *Teva* appeal, and (2) the 30-month stays as to those Defendants would have expired well before the *Teva* appeal would have been decided. Here, it is far too late for Collegium to join in the *Teva* appeal, which appeal should be decided long before the expiration of Collegium's 30-month stay.

and expert discovery into both technical and economic issues, and taxing the resources of the Court and the parties. Given the imminent decision from the Federal Circuit in the *Teva* appeal, there is no good reason for requiring these onerous proceedings at this time.[6]

Immediate entry of judgment as Collegium requests could also multiply proceedings before the Federal Circuit. If this Court were to determine that collateral estoppel applies, and then enter a partial final judgment pursuant to Rule 54(b), Purdue would then be forced to appeal *that* judgment to the Federal Circuit in order to preserve its rights: If the Court were to issue the requested immediate Rule 54(b) judgment, and the Federal Circuit then reverses in the *Teva* appeal, the Federal Circuit would have to further unwind Purdue's appeal from the hasty Rule 54(b) judgment Collegium now seeks. Engaging the Federal Circuit's appellate processes for an appeal that would be completely unnecessary no matter how the *Teva* appeal comes out is not a wise or efficient use of the parties'—or the federal courts'—resources. This is yet another reason why, as noted above, courts have recognized that "the prudent course is to stay any determination on the second action while the appeal is resolved." *Hynix*, 2009 U.S. Dist. LEXIS 10939, at *19.

By contrast, if the Court stays proceedings on the Listed Patents until final resolution of the *Teva* appeal, most of these costs and premature proceedings can be avoided. The 30-month stay would remain intact, thereby obviating any immediate need for a preliminary injunction motion on the other two patents, and Purdue would not be required to take a premature appeal to the Federal Circuit from the Rule 54(b) judgment. Relative to the potential risks of a premature

[6] In addition, if a Rule 54(b) judgment were entered and Collegium launched, but the Listed Patents are later found valid in the *Teva* appeal or on a remand, Purdue would seek damages against Collegium for its premature launch.

judgment, temporarily staying proceedings on the Listed Patents is prudent and promotes efficiency.

Notably, any disruption to this case due to a temporary stay of proceedings on the Listed Patents will be minimal. This litigation is in its earliest stages—pleadings only recently closed, and no discovery or initial scheduling conference has been set. *See Boston Heart Diagnostics*, 2014 U.S. Dist. LEXIS 67711, at *11-12 (granting a stay pending patent reexamination where "[t]he Court has not even held a scheduling conference" and the parties had not "engage[d] in discovery or set dates for a *Markman* hearing or trial"); *Body Science*, 2012 U.S. Dist. LEXIS 158835, at *18 (granting stay where "13 months had passed since the lawsuit was filed, and the parties were in the early stages of discovery").

Even with a stay as to the Listed Patents, the parties will proceed with litigation for the '497 and '933 patents during that stay. As part of the '933 patent discovery, which shares the same specification as the Listed Patents but claims different subject matter, Purdue will produce documents relating to the Listed Patents that were already produced in previous litigation (subject to a complete, negotiated discovery schedule approved by the Court). Thus, in the event of reversal in the *Teva* appeal, Collegium will not suffer any discovery delay in connection with the Listed Patents because it will already have those documents in hand. *E.g.*, *SmithKline*, 2004 U.S. Dist. LEXIS 13907, at *34-35 (staying one patent, but proceeding on others). Accordingly, the requested stay will impose little, if any, delay in the proceedings in this case.

C. Expedited Hearing is Unnecessary

There is no reason for this Court to rearrange its calendar to accommodate Collegium's request for expedited hearing. The Federal Circuit is likely to issue its decision soon, and

Collegium cannot launch until April 2016, due to Purdue's data exclusivity, in any event. Collegium's Motions can be resolved at the Court's convenience.

Collegium's motion to expedite relies heavily on bold predictions about Xtampza™ ER's superior properties and anticipated launch, all of which are speculative. The crux of Collegium's argument boils down to the simple fact that Collegium wants to enter the market as soon as possible, because that has "significant financial consequences for Collegium." ECF No. 24 at 3. Collegium's financial desires do not justify rushing to a premature judgment that would impose considerable costs on the parties and the courts.

Collegium's attacks on OxyContin® and its abuse-deterrent properties to bolster Collegium's product ring hollow given that Collegium relied on Purdue's OxyContin® clinical data to seek FDA approval. The study that Collegium cites here—as well as others—actually confirmed that reformulated OxyContin® has significantly reduced abuse. *See, e.g.*, Holdreith Ex. D (ECF No. 25-6) at 4 ("'Most people that I know don't use OxyContin to get high anymore.'"). Ultimately, OxyContin® remains the only FDA-approved abuse-deterrent, extended-release form of oxycodone, and no other generic or alternative oxycodone drug has launched.

As reasons to expedite hearing, Collegium contends that there is a public need for its product and insists that the policy behind the Hatch-Waxman Act is to make drugs like Xtampza™ ER available to the public as soon as possible. *See* ECF No. 24 at 1. But this is not a typical Hatch-Waxman case, in which a company intends to bring lower cost generic drugs to market against the new drugs developed by the pioneering research of innovators like Purdue. *See Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370-71 (Fed. Cir. 2002) (explaining the policy behind the Hatch-Waxman Act). Collegium is offering a different product, although it

depends on Purdue's research for approval. The 30-month stay is an important tool for allowing the parties time to resolve their patent disputes before a premature launch. To the extent Collegium contends that the Hatch-Waxman Act favors quick entry of new drugs without due respect for patent rights, that view is incorrect.

Despite Collegium's representations to this Court that it must launch Xtampza™ ER immediately and "would be greatly prejudiced by any delay" (ECF No. 24 at 3), it has *in fact* told the public and its investors that it will not launch until April 2016. *See* Exs. D-F. As recently as November 12, Collegium publicly repeated its "potential" launch date of April 2016, which is when Purdue's data exclusivity runs out. Even then, Collegium qualified this as a "potential" date, not a guaranteed one. Its current claims, made to this Court, about its supposed need for expedited hearing and immediate judgment, contradict what it has told the investing public—that Xtampza™ ER cannot be on store shelves until at least April 2016. So the hasty judgment that Collegium seeks will give it no immediate benefits, but will only burden the parties and the federal judiciary with more, and unnecessary, litigation. Accordingly, there can be no undue prejudice to Collegium from a brief stay pending appeal.

IV. CONCLUSION

For the foregoing reasons, both of Collegium's motions should be denied, and Purdue's motion for a partial stay pending the *Teva* appeal should be granted.

Dated: November 23, 2015

Respectfully submitted,
PURDUE PHARMA L.P.,
THE P.F. LABORATORIES, INC.,
PURDUE PHARMACEUTICALS L.P., AND
RHODES TECHNOLOGIES,

By their counsel,

/s/ Christopher M. Morrison

Christopher M. Morrison (BBO# 651335)
JONES DAY
100 High Street
21st Floor
Boston, MA 02110
Telephone: (617) 960-3939
Facsimile: (617) 449-6999
cmorrison@jonesday.com

CERTIFICATE OF SERVICE

I hereby certify that, on this 23d day of November 2015, the foregoing document was served upon all counsel of record through this Court's electronic filing system as identified in the Notice of Electronic Filing, and paper copies will be sent to those indicated as nonregistered participants hereby certify that this document will be served by e-mail on all counsel of record on November 23, 2015.

/s/ *Christopher M. Morrison*
Christopher M. Morrison